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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,875	10/26/2000	Robert H. Kincaid	10002206-1	5404

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AGILENT TECHNOLOGIES
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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,875	Applicant(s) KINCAID, ROBERT H.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 50-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restrictions

1. Applicant's election without traverse of Group III, claims 30-49, filed 19 December 2001 in Paper No. 4 is acknowledged. Claims 1-29 and 50-84 are withdrawn from further consideration.

Claims 30-49 are discussed below.

Information Disclosure Statement

2. The references listed on the 1449 received 26 October 2000 have been reviewed and considered. A copy of the initialed 1449 is enclosed with this action.

Drawings

3. This application has been filed with drawings which are acceptable for examination purposes. Formal drawings may be required when the application is allowed.

Specification

4. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 30-49 are indefinite in Claim 30 because the claim is drawn to a method of making array but the claim does not recite method steps of array making. The claims are further indefinite because it is unclear whether the microarray comprises the control and test probes. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested that Claim 30 be amended to recite positive and active steps for making a microarray e.g. attaching probes at a location on a surface (page 9, lines 12-20).

b. Claims 30-49 are indefinite in Claim 30, line 4 for the recitation "the control probe being associated with a control label" because "being associated with" is a non-specific relational phrase. Therefore, the relationship between the control probe and the control label is undefined. It is suggested that Claim 30 be amended to define the relationship e.g. replace "associated with" with "directly or indirectly attached" (page 7, lines 5-20).

c. Claims 30-49 are indefinite in Claim 30, line 6 for the recitation "each feature location" because the recitation lacks proper antecedent basis in the preceding steps of the claim. It is suggested that Claim 30 be amended to provide proper antecedent basis e.g. in line 3, after "features" insert "each feature having a location".

d. Claims 31-33 are each indefinite for the recitation "the surface within each feature" because the recitation lacks proper antecedent basis in Claim 30. It is suggested that Claims 31-33 be amended to provide correct antecedent basis e.g. replace "the" with "a".

e. Claims 34is indefinite for the recitation "each feature location" because the recitation lacks proper antecedent basis in Claim 30. It is suggested that Claim 30 be amended to provide proper antecedent basis e.g. in line 3, after "features" insert "each feature having a location".

f. Claims 32-34 and 36 are each indefinite for the recitation "indirectly associating the (a) control label" because "associating" is a non-specific relational term. Therefore, it is unclear what structural relationship is being claimed. It is suggested that Claims 32-34 and 36 each be amended to define the relationship e.g. replace "associating" with "directly or indirectly attaching" (page 7, lines 5-20).

g. Claim 34 is indefinite in line 6 for the recitation "the labeled control target material" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 34 be amended to provide proper antecedent basis e.g. replace "control" with "control-specific".

h. Claim 38 is indefinite in line 28 for the recitation "at each feature location" because the recitation lacks proper antecedent basis in Claim 30. It is suggested that either Claim 30 or Claim 38 be amended to provide proper antecedent basis e.g. in Claim 30, line 3, after "features" insert "each feature having a location" or in Claim 38, delete "location".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 30-41 and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al (WO 97/27317, published 31 July 1997).

Regarding Claim 30, Lockhart et al disclose a method of making a microarray comprising: providing a control probe in an array pattern of features on a surface of a substrate; and providing an oligomer test probe to each feature such that each feature comprising a control probe and a test probe i.e. constant region and variable region (page 71, lines 1-8 and Fig. 13a) wherein the control probe is associated with a control label that emits a control signal when excited by a light (Fig. 13a "label b").

Regarding Claim 31, Lockhart et al disclose the method comprising adding one end of the control probe to the substrate and directly labeling the control probe with a control label (page 72, lines 23-31 and Fig. 13 b). The claims are given the broadest reasonable interpretation consistent with the broad claim language "directly labeling" and specification wherein "directly labeling" is not defined (see page 7, lines 6-14). Given the broadest reasonable interpretation of the claims, the ligation labeling of Lockhart et al is encompassed by the claimed "directly labeling".

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 32, Lockhart et al disclose the method comprising adding one end of the control probe to the surface of the substrate and indirectly associating the control label to the control probe by hybridization when exposed to a control-specific target material comprising the control label (page 6, lines 13-23, page 71, line 1-page 72, line 31 and Fig. 13a-b).

Regarding Claim 33, Lockhart et al disclose the method comprising adding one end of the control probe to the surface of the substrate; directly labeling the control probe with a control label; indirectly associating a control label to the control probe by hybridization when exposed to a hybridization mixture comprising a labeled control-specific target material complementary to the control probe and the labeled test target sample comprises the test label (page 71, line 1-page 72, line 31 and Fig. 13a-b).

Regarding Claim 34, Lockhart et al disclose the method comprising adding one end of the control probe to the surface of the substrate; adding the oligomer test probe to each feature and indirectly associating the control label to the control probe and test label to the test probe by hybridization when exposed to a hybridization mixture comprising a labeled control-specific target material complementary to the control probe and the labeled test target sample comprises the test label (page 71, line 1-page 72, line 31and Fig. 13a-b).

Regarding Claim 35, Lockhart et al disclose the method comprising adding the oligomer test probe to each feature of the substrate and directly labeling the test probe with a test label (Fig. 13a, "label b").

Regarding Claim 36, Lockhart et al disclose the method comprising adding an oligomer test probe to each feature of the substrate and indirectly associating a test label with the oligomer test probe by hybridization when exposed to a test target material that comprises the test label (Fig. 13a, "label a").

Regarding Claim 37, Lockhart et al disclose the method wherein the step of providing the control probe comprise the step of adding one end of the control probe to the surface of the substrate and the step of proving the oligomer test probe comprises the step of adding the oligomer test probe to an opposite end of the control probes such that the control probe is a stilt that extends between the oligomer test probe and the surface such that each feature comprises the control stilt and test probe (Fig. 13 a-b).

Regarding Claim 38, Lockhart et al disclose the method wherein the step of providing the control probe comprise the step of adding one end of the control probe to the surface of the substrate and the step of proving the oligomer test probe comprises the step of adding one end of the test probe to the surface of the substrate such that each feature comprises the control stilt and test probe i.e. Lockhart et al the method comprising "adding" the one end to the surface because the control probe (constant region) to which the test probe is attached is on the surface of the substrate (Fig. 13 a-b).

Regarding Claim 39, Lockhart et al disclose the method wherein the step of providing the control probe comprises presynthesizing the control probe and attaching one end to the surface of the substrate within each feature i.e. mechanically coupling (page 47, lines 14-15).

Regarding Claim 40, Lockhart et al disclose the method wherein the step of providing the oligomer test probe comprises presynthesizing the test probe and attaching one end to the surface of the substrate within each feature (page 62, lines 20-23).

Regarding Claim 41, Lockhart et al disclose the method wherein the step of attaching the presynthesized oligomer test probe comprises attaching the presynthesized oligomer to an opposite end of the presynthesized control probe (page 72, lines 23-31 and Fig. 13 a-b).

Regarding Claim 44, Lockhart et al disclose the method wherein the step of providing the control probe comprises synthesizing the control probe *in situ* within each feature (page 47, line 13).

Regarding Claim 45, Lockhart et al disclose the method wherein the step of providing the test probe comprises presynthesizing the test probe and attaching the presynthesized test probe within each feature (Fig. 13 a-b)

Regarding Claim 46, Lockhart et al disclose the method wherein the step of attaching the presynthesized test probe comprises attaching to an unattached end of the in situ synthesized control probe (page 62, lines 20-23, page 71, lines 9-28 and Fig. 13 a-b).

Regarding Claim 47, Lockhart et al disclose the method of Claim 44 wherein the step of providing the oligomer test probe (i.e. variable region) comprises synthesizing the oligomer *in situ* within each feature (page 71, lines 9-14 and Fig. 13a).

Regarding Claim 48, Lockhart et al disclose the method of Claim 47 wherein *in situ* synthesized test probe is synthesized on an unattached end of the *in situ* synthesized control probe (page 71, lines 9-14 and Fig. 13a).

10. Claims 30-36, 38-40, 42, 44 and 47are rejected under 35 U.S.C. 102(e) as being anticipate by Gentalen et al (U.S. Patent No. 6,306,643 B1, filed 24 August 1998).

Regarding Claim 30, Gentalen et al disclose a method of making a microarray comprising: providing a control probe in an array pattern of features on a surface of a substrate; and providing an oligomer test probe to each feature such that each feature comprising a control probe and a test probe i.e. common probe and variable probe (Column 14,

line 59-Column 15, line 4) wherein the control probe is associated with a control label that emits a control signal when excited by light (Column 11, lines 1-11).

Regarding Claim 31, Gentalen et al disclose the method comprising adding one end of the control probe to the substrate and directly labeling the control probe with a control label (Column 11, lines 1-11). The claims are given the broadest reasonable interpretation consistent with the broad claim language "directly labeling" and specification wherein "directly labeling" is not defined (see page 7, lines 6-14). Given the broadest reasonable interpretation of the claims, the labeling of Gentalen et al is encompassed by the claimed "directly labeling".

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 32, Gentalen et al disclose the method comprising adding one end of the control probe to the surface of the substrate (Column 11, lines 46-48) and indirectly associating the control label to the control probe by hybridization when exposed to a control-specific target material comprising the control label (Column 11, lines 1-11).

Regarding Claim 33, Gentalen et al disclose the method comprising adding one end of the control probe to the surface of the substrate (Column 11, lines 46-48); directly labeling the control probe with a control label (Column 11, lines 1-11); indirectly associating a control label to the control probe by hybridization when exposed to a hybridization mixture comprising a labeled control-specific target material complementary to the control probe and the labeled test target sample comprises the test label (Column 11, lines 1-11).

Regarding Claim 34, Gentalen et al disclose the method comprising adding one end of the control probe to the surface of the substrate (Column 11, lines 46-48); adding the oligomer test probe to each feature and indirectly associating the control label to the control probe and

test label to the test probe by hybridization when exposed to a hybridization mixture comprising a labeled control-specific target material complementary to the control probe and the labeled test target sample comprises the test label (Column 11, lines 1-11).

Regarding Claim 35, Gentalen et al disclose the method comprising adding the oligomer test probe to each feature of the substrate and directly labeling the test probe with a test label (Column 11, lines 1-11). The claims are given the broadest reasonable interpretation consistent with the broad claim language "directly labeling" and specification wherein "directly labeling" is not defined (see page 7, lines 6-14). Given the broadest reasonable interpretation of the claims, the labeling of Gentalen et al is encompassed by the claimed "directly labeling".

Regarding Claim 36, Gentalen et al disclose the method comprising adding an oligomer test probe to each feature of the substrate and indirectly associating a test label with the oligomer test probe by hybridization when exposed to a test target material that comprises the test label (Column 11, lines 1-11).

Regarding Claim 38, Gentalen et al disclose the method wherein the step of providing the control probe comprises the step of adding one end of the control probe to the surface of the substrate; and the step of providing the test probe comprises adding one end of the oligomer test probe to the surface of the substrate at each location such that each feature comprises the control probe and the oligomer test probe (Column 14, line 59-Column 15, line 4).

Regarding Claim 39, Gentalen et al disclose the method wherein the step of providing the control probe comprises presynthesizing the control probe and attaching one end to the surface of the substrate within each feature (Column 11, lines 46-48).

Regarding Claim 40, Gentalen et al disclose the method wherein the step of providing the oligomer test probe comprises presynthesizing the test probe and attaching one end to the surface of the substrate within each feature (Column 11, lines 46-48).

Regarding Claim 42, Gentalen et al disclose the method wherein the step of providing the oligomer test probe comprises synthesizing the test probe *in situ* within each feature (Column 11, lines 48-61).

Regarding Claim 44, Gentalen et al disclose the method wherein the step of providing the control probe comprises synthesizing the control probe *in situ* within each feature (Column 11, lines 48-61).

Regarding Claim 47, Gentalen et al disclose the method of Claim 44 wherein the step of providing the oligomer test probe comprises synthesizing the test probe *in situ* within each feature (Column 11, lines 48-61).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 42, 43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al (WO 97/27317, published 31 July 1997).

Regarding Claims 42, 43 and 49, Lockhart et al teach a method of making a microarray comprising: providing a control probe in an array pattern of features on a surface of a substrate; and providing an oligomer test probe to each feature such that each feature comprising a control probe and a test probe i.e. constant region and variable region (page 71,

lines 1-8 and Fig. 13a) wherein the control probe is associated with a control label that emits a control signal when excited by a light (Fig. 13a "label b") wherein the step of providing the control probe comprises presynthesizing the control probe and attaching one end to the surface of the substrate within each feature (page 47, lines 14-15) and they teach *in situ* synthesis of probes on the array using well known techniques (page 62, lines 19-31) e.g. a fully synthesized portion of the probe is attached to the support followed by *in situ* synthesis of the remaining portion of the probe (page 65, lines 24-29) which clearly suggests attaching a presynthesized control portion of the probe and synthesizing *in situ* the test portion of the probe, but they do not specifically teach that the presynthesized control probe is attached on the surface and the test probe is synthesized *in situ* at the feature. Because *in situ* synthesis is time consuming and costly (see Lockhart et al, page 59, lines 18-28) and because the control probes on the array consist of the same constant domain, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Lockhart et al by simply attaching presynthesized control probes to all features of the array as they suggest (page 65, lines 24-29) and thereafter synthesizing test probes of differing sequence on the opposite end of the control probe. One skilled in the art would have been motivated to apply the suggested synthesis of Lockhart et al to their probes thereby saving the time and labor costs of *in situ* synthesis for the control portion of their probes and hence for the obvious benefits of economy of time and labor.

NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

13. This application contains sequence disclosures (e.g. page 24) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given A PERIOD OF TIME WHICH IS CO-EXTENSIVE WITH THE TIME FOR REPLY TO THE ABOVE OFFICE ACTION to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

14. No claim is allowed.

15. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 9, 2002